

**REMARKS****“SAME INVENTION” DOUBLE PATENTING REJECTION**

Claims 26, 27 and 29 were rejected under 35 U.S.C. 101 as claiming the same invention as Claims 1, 3 and 4 of U.S. Patent No. 6,432,383 (the ‘383 Patent). This rejection is in error and should be withdrawn.

(1) **THE REJECTION DOES NOT MEET THE LEGAL STANDARD FOR A  
“SAME INVENTION” DOUBLE PATENTING REJECTION.**

As recognized by the Examiner, Claims 26, 27 and 29 of the instant application have an additional limitation beyond Claims 1, 3 and 4 of the ‘383 Patent. This additional limitation is that the insulin is administered to the buccal mucosa...”while resisting substantial inhalation of said insulin.” The Examiner has stated that this additional limitation is inherent in the ‘383 Patent, which it is not.

Inherency requires that the unstated limitation be necessarily included in the prior art reference. *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1373, 62 USPQ2d 1865 (Fed. Cir. 2002). Inherency cannot be based on a mere probability or possibility. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 USPQ 303 (Fed. Cir. 1983).

The Examiner’s position ignores the fact that a patient may inhale, exhale or hold their breath while insulin is administered to their buccal mucosa. Resisting substantial inhalation is only one of three possibilities. Thus, this limitation is, at most, a possibility; it is not even a probability and certainly not a necessary limitation.

As a result, the “same invention” double patenting rejection is legally improper under the Patent Law.

(2) **THE REJECTION IS CLEARLY INCONSISTENT WITH THE BOARD OF  
APPEALS DECISION OF FEBRUARY 25, 2004 IN THE INSTANT  
APPLICATION.**

In its Decision, the Board stated that Claim 27 “defines a particular process comprising, among other things, the step of ‘resisting substantial inhalation’.” Page 5, paragraph 1. Thus, the

Board recognized that "resisting substantial inhalation" was an additional step and limitation in Claim 26 over the prior art.

Furthermore, the Board was well aware of the '383 Patent. Indeed, in its Decision, it asks the Examiner to consider whether a rejection should be made for "obviousness-type double patenting" but not "same invention" double patenting. Page 7, paragraphs 1 and 2. Clearly, if the Board felt that a "same invention" rejection should have been even considered, it would have stated so.

The "same invention" double patenting rejection should be withdrawn for the reasons presented above.

#### "OBVIOUSNESS-TYPE" DOUBLE PATENTING REJECTION

The Examiner also rejected Claims 26-34, 36 and 37 based on "obviousness-type" double patenting over the '383 Patent.

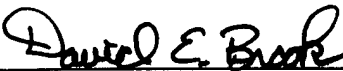
Even though Applicant disagrees with this rejection, a Terminal Disclaimer over the '383 Patent is submitted concurrently herewith, together with the requisite fee, to obviate this rejection.

#### CONCLUSION

The claims in this application are in condition for allowance, and it is respectfully requested that the Examiner pass this application to issue. If the Examiner would like to discuss any matter relating to this application, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

David E. Brook

Registration No. 22,592

Telephone: (978) 341-0036

Facsimile: (978) 341-0136

Concord, MA 01742-9133

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